

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARRAY BIOPHARMA INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 23-625 (GBW)
)	
TEVA PHARMACEUTICALS, INC.,)	
)	
Defendant.)	

**PLAINTIFF ARRAY BIOPHARMA INC.'S
ANSWERING BRIEF IN OPPOSITION TO DEFENDANT'S MOTION TO STAY**

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Teva's brief acknowledges that, absent a stay, there are two straightforward paths this case can follow: The Court can either (1) permit Array to revisit in this case the claim construction decision regarding Crystallized Binimetinib Patents that this Court issued in the pending case against Alembic and Sandoz, or (2) apply its prior claim construction in this case and enter final judgment of non-infringement in Teva's favor, permitting Array to appeal to the Federal Circuit.¹ Teva's Motion fails to justify suspending this case indefinitely. Accordingly, the Court should deny Teva's Motion and either allow the case to proceed or enter judgment and allow Array to appeal the Court's dispositive claim construction.

I. NATURE AND STAGE OF THE PROCEEDINGS AND STATEMENT OF FACTS

This is an action brought by Array alleging infringement by Teva of United States Patent Nos. 9,562,016; 9,598,376; and 9,980,944 (the "Crystallized Binimetinib Patents"). This case is related to litigations brought by Array against Alembic Pharmaceuticals Limited and Sandoz Inc., consolidated as *Array BioPharma, Inc. v. Alembic Pharmaceuticals Ltd.*, C.A. No. 22-1277-GBW (D. Del.) (the "*Alembic/Sandoz*" case), where Array is asserting three patents not at issue here (the "Huang Patents"), as well as the three Crystallized Binimetinib Patents. In the *Alembic/Sandoz* case, this Court construed the claim term "[c]rystallized 6-(4-bromo-2-fluorophenylamino)-7-fluoro-3-methyl-3H-benzimidazole-5-carboxylic acid (2-hydroxyethoxy)-amide" (i.e., "crystallized [binimetinib]") as "[b]inimetinib in a crystalline form resulting from the use of a solvent mixture of ether and optionally an alcohol." *Alembic/Sandoz*, D.I. 93, 94. Array, Sandoz, and Alembic stipulated in *Alembic/Sandoz* that the Alembic and Sandoz ANDA products at issue would not infringe any of the asserted claims of the Crystallized Binimetinib Patents, as so

¹ Alternatively, Teva can end the litigation entirely by changing its Paragraph IV certification with respect to the Crystallized Binimetinib Patents to a Paragraph III Certification.

construed, and Array's claims with respect thereto were dismissed without prejudice. *Alembic/Sandoz*, D.I. 131, 133, 134. Only the Huang Patents remain at issue in *Alembic/Sandoz*. Trial in *Alembic/Sandoz* has been scheduled for June 2025, and the 30-month stay in that case does not expire until December 2025.

Teva moves to stay this case in view of the Court's claim construction order in *Alembic/Sandoz*. See Teva's Motion to Stay filed November 8, 2024. D.I. 18 ("Teva's Motion"). Array admits that if the Court adopts in this case its construction of "crystallized [binimetinib]" in *Alembic/Sandoz*, Teva's proposed ANDA product would not infringe any of the asserted claims of the Crystallized Binimetinib Patents. But, as Teva concedes (Teva's Motion at 6), Array is not bound by that construction here because there is no final judgment in that case. Nevertheless, rather than permit Array to prosecute the case it brought against Teva and revisit the dispositive claim construction that this Court arrived at in the *Alembic/Sandoz* case or ask the Court to enter judgment in Teva's favor, Teva moves this Court to stay this case until final resolution of the *Alembic/Sandoz* case, including any appeals to the Federal Circuit.

II. SUMMARY OF ARGUMENT

1. Any purported simplification of the issues is too speculative to warrant a stay.
2. The lack of activity in this case to date does not favor granting a stay as it ordinarily would, given that the claim construction order in the *Alembic/Sandoz* case forecloses a finding of infringement by Teva if adopted here.
3. Array would be unduly prejudiced by having to wait over two years to enforce its patent rights pending an appeal that may not simplify the issues.

III. ARGUMENT: TEVA HAS NOT MET ITS BURDEN OF ESTABLISHING THAT A STAY IS WARRANTED

A. Legal Standards

The decision of whether to grant a stay rests within the sound discretion of the Court as a product of its inherent power to manage its own docket so as to conserve judicial resources. *Davol, Inc. v. Atrium Med. Corp.*, No. CIV.A. 12-958-GMS, 2013 WL 3013343, at *1 (D. Del. June 17, 2013). In exercising this discretion, the Court must weigh and balance the competing interests of the parties. *See Landis v. North American Co.*, 299 U.S. 248, 255 (1936). As Teva observes, the factors that courts typically consider in deciding how to exercise this discretion include: (1) whether a stay will simplify the issues and trial of the case, (2) whether discovery is complete and a trial date has been set, and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party. *See, e.g., St. Clair Intellectual Property v. Sony Corp.*, 2003 WL 25283239, at *1 (D. Del. Jan.30, 2003). “The proponent of a stay bears the burden of establishing its need.” *Clinton v. Jones*, 520 U.S. 681, 708, (1997). For the reasons set forth below, Teva has not met its burden of establishing that this Court should grant a stay.

B. Factor 1: Any Simplification of the Issues Is Speculative

Teva’s simplification argument assumes the outcome Teva wants—that the Court’s claim construction in *Alembic/Sandoz* will stand. Teva ignores that there will be no issue simplification—and only delay—if the Federal Circuit vacates or alters the Court’s construction of “crystallized [Binimetinib].”² *See Rogers v. Experian Info. Sols., Inc.*, No. CV 22-1520-CFC,

² Contrary to Teva’s suggestion, Array does not intend to rely on Teva’s accused product in proposing a construction for “crystallized [binimetinib].” Teva’s Motion at 4. Nor does Array plan merely to repeat the claim construction arguments made in the *Alembic/Sandoz* case. Rather, Array seeks to revisit in this case the construction of “crystallized [binimetinib]” in light of the Court’s decision in the other case, and the evidence and arguments propounded there by Alembic and

2024 WL 894857, at *1 (D. Del. Mar. 1, 2024) (“In considering the prospects for simplification, courts assess all possible outcomes, not just the potential outcome most favorable to the party seeking the stay.”); *Pragmatus AV, LLC v. Yahoo! Inc.*, No. CIV.A. 11-902-LPS, 2013 WL 2372206, at *3 (D. Del. May 30, 2013) (“In light of the speculative nature of the prospect for simplification of the issues were a stay granted, and the greater likelihood that a stay would hinder judicial efficiency . . . , the Court finds that this factor weighs against a stay.”).

Additionally, no appeal has been filed in the *Alembic/Sandoz* case—indeed, that case is more than a year away from being ready for appeal. Moreover, if those cases settle, there will be no appeal of the claim construction in that case and no simplification of issues in this case, similar to the situation in the many decisions in this district that refuse to stay cases pending review by the PTAB until review is actually granted. *Cf. Advanced Microscopy Inc.*, C.A. No. 15–516–LPS–CJB, 2016 WL 558615, at *1 (D. Del. Feb. 11, 2016) (“Unless and until the PTAB institutes IPR and CBM proceedings based on the petitions, any expected simplification rests on speculation that such institution will occur.”); *Universal Secure Registry, LLC v. Apple Inc.*, C.A. No. 17-585-CFC-SRF, 2018 WL 4486379, at *2 (D. Del. Sept. 19, 2018) (“If no review is instituted, the asserted basis for a stay will fall away.”). Teva can only conjecture as to whether, when, and to what extent, the issues in this case will be simplified by a Federal Circuit appeal in *Alembic/Sandoz*.

C. Factor 2: The Stage of the Case Factor Is Neutral at Best

Although the Court has not yet entered a schedule in this case, the situation here differs significantly from the usual early stage litigation. The fact that the *Alembic/Sandoz* case has

Sandoz. Array respectfully submits that the Court relied on representations by counsel that were not supported by evidence before the Court.

proceeded through claim construction—and resulted in a construction that would foreclose Array’s claims here against Teva—effectively makes this case more advanced than the typical case where discovery has yet to begin. This case is either at the Markman stage (if the Court hears the parties with respect to the particulars of this Court’s prior construction of “crystallized [binimetinib]”), or the case is over. In other words, the lack of activity in this case to date does not favor granting a stay as it ordinarily would.

D. Factor 3: Array Would Be Prejudiced by a Stay

The third factor weighs against granting Teva’s Motion. “[A] patentee has an interest in prompt enforcement of its patent rights.” *IOENGINE*, 2020 WL 6270776, at *3; *Cooper Notification, Inc. v. Twitter, Inc.*, 2010 WL 5149351, at *3 (D. Del. Dec. 13, 2010) (denying motion to stay pending reexamination that was still in the early stages despite potential to simplify the case because the reexamination process has a lengthy, non-fixed timeline). The longer a patentee must wait to enforce those patent rights—here likely more than two years before the *Alembic/Sandoz* case can be appealed and a final decision issued by the Federal Circuit—the greater the risk of undue prejudice. *Cf. UCB, Inc. v. Zydus Pharms. (USA) Inc.*, C.A. No. 09-865-LPS, 2017 WL 4310860, at *2 (D. Del. Sept. 28, 2017) (noting that “[t]he risk of undue prejudice to Plaintiffs would be much greater” if the expected length of the other proceeding was longer). This is especially true when it is only speculative that the issues would be simplified by a stay. *RideShare Displays, Inc. v. Lyft, Inc.*, No. CV 20-1629-RGA-JLH, 2021 WL 7286931, at *2 (D. Del. Dec. 17, 2021) (“[W]hile the mere potential for delay is insufficient to establish undue prejudice, here a stay would almost certainly cause delay, and the prejudice accompanying that delay is undue because, as I said earlier, it’s only speculative that the issues would be simplified.”). Array is entitled to a determination of its patent rights and the future of generic competition by

Teva so that it can plan accordingly. A stay will thus prejudice Array. By contrast, Teva has not shown that denial of its motion will cause it any prejudice.

Finally, given Teva's statement that it will not "bring its proposed ANDA product to market before the expiration of the Huang Patents, which are not expected to expire until the year 2030 or later" (Teva's Motion at 6–7), Teva could, for now, amend its Paragraph IV certification to a Paragraph III certification. That would end this litigation immediately.

E. The Cases Cited by Teva Are Distinguishable

The cases relied on by Teva do not support a stay here. Importantly, in all of *UCB*, *454 Life Sciences*, *Personal Genomics*, and *Choon's Design*, the parallel proceeding had progressed much further. In *UCB*, defendant Zydus moved for a stay in an ANDA action pending resolution of two already ongoing review proceedings: (1) a Federal Circuit appeal of the district court's post-trial judgment that the asserted patent was infringed and not invalid and (2) a reexamination of the asserted patent with an outstanding office action rejecting all claims as obvious. *UCB*, 2017 WL 4310860, at *1. Judge Stark stayed that case, but only until resolution of the *already pending* Federal Circuit appeal—not through resolution of the reexamination proceeding. The court reasoned that the risk of undue prejudice to the plaintiff would be increased by the extended time—potentially years—that the reexamination process would take. *Id.*, at *2. Moreover, the Federal Circuit appeal in *UCB* was at an advanced stage, with oral argument having already taken place. *Id.*, at *1. In *Personal Genomics*, the defendant granted a stay pending appeal of two IPRs after the appeals had *already been filed* (*Personal Genomics Taiwan, Inc. v. Pacific Biosciences of Cali., Inc.*, C.A. No. 19-1810-GBW-MPT, 2022 WL 4245532, at *1 (D. Del. Sept. 15, 2022)). In *Choon's Design*, a stay was granted pending resolution of a parallel appeal to the Federal Circuit that was *already pending*. *Choon's Design Inc. v. Tristar Prod., Inc.*, C.A. No. 14-10848-VAR, 2018 WL 11351661, at *1 (E.D. Mich. July 13, 2018).

Similarly, in *454 Life Sciences Corp. v. Ion Torrent Systems, Inc.*, C.A. No. 15-595-LPS, 2016 WL 6594083, at *2 (D. Del. Nov. 7, 2016), the defendant moved for a stay of the district court action *after IPRs had been instituted*. The court pointed out that the PTAB is statutorily required to issue its Final Written Decisions within eight months of granting the stay. *Id.* That case is also distinguishable because there the court reasoned that issue simplification was guaranteed where the defendant would be estopped from asserting in the district court any ground for invalidity that they raised or reasonably could have raised during the IPR proceedings. *Id.* at *3.

Here, by contrast, appeal of the claim construction in *Alembic/Sandoz* is unlikely even to begin for about a year.³ Current Federal Circuit statistics indicate that the appeal itself will then take approximately another 15 months from the time the appeal is filed (Ex. A). Thus, unlike in the cases Teva relies upon where the stays were expected to be relatively short, a stay of this case pending appeal of the *Alembic/Sandoz* claim construction ruling is likely to last more than two years. And, the expected appeal may not result in any issue simplification at all if the Federal Circuit vacates or alters the Court's construction of "crystallized [Binimetinib]" or if the parties to *Alembic/Sandoz* settle such that no appeal is ever decided.

IV. CONCLUSION

For these reasons above, Array respectfully requests that the Court deny Teva's Motion to Stay.

³ Trial in *Alembic/Sandoz* is scheduled for June 2025. The parties will then require time to prepare and file post-trial briefs, and the Court will need time to issue its opinion.

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November 22, 2024

CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on November 22, 2024, upon the following in the manner indicated:

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